Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of efficacy of Maa-al-shaeer (An Iranian medicine product based on barley seeds) in preventing and reducing the severity of radiotherapy-induced dysuria in prostate cancer patients; a double-blind randomized clinical trial

Protocol summary

Study aim
Evaluation of the efficacy of Maa-al-shaeer in preventing and reducing the severity of radiotherapy-induced dysuria in prostate cancer

Design
A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 70 patients. Randomization is done using R software version 4.1.2 and the randomization list generated using R software will be used.

Settings and conduct
Prostate cancer patients candidates for radiotherapy (in the radiotherapy center of Shohada-e-Tajrish Hospital), without the exclusion criteria, will be included in the study and assigned to the intervention or control group randomly. The study is double-blind, and patients, healthcare providers, researchers, and analysts are all blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Over 18 years old 2. Prostate cancer 3. Candidate for radiation therapy 4. Consciousness Criteria for not entering the study: 1. Unconsciousness or unable to report the dysuria 2. Urine catheter 3. Urine analysis test with infection evidence 4. Diabetes Mellitus 5. Dysuria 6. History of drug sensitivity 7. Metastasis 8. Chemotherapy at the same time 9. Hematuria 10. Severe cardiovascular, pulmonary, hepatic, and kidney disease needs to be treated 11. Not participating in the study

Intervention groups
The participants, twice a day, each time, a measure (equivalent to 7.5 cc) of powder (Maa-al-shaeer in the intervention group or placebo in the control group) dissolve in a glass of water and consume it. The duration of using the drug or placebo is 4 weeks from the beginning of radiotheraphy.

Main outcome variables
Dysuria, Quality of life, The number of phenazopyridine tablets which was taken, Treatment satisfaction (secondary outcome)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190608043840N1**
Registration date: **2023-01-22, 1401/11/02**
Registration timing: **prospective**

Last update: **2023-01-22, 1401/11/02**
Update count: **0**

Registration date
2023-01-22, 1401/11/02

Registrant information

Name
Vida Nazari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2230 3841

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-01, 1401/11/12

Expected recruitment end date
2023-07-01, 1402/04/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of efficacy of Maa-al-shaeer (An Iranian medicine product based on barley seeds) in preventing and reducing the severity of radiotherapy-induced dysuria in prostate cancer patients; a double-blind randomized clinical trial

Public title
Evaluation of the efficacy of Maa-al-shaeer (product based on barley seeds) on radiotherapy induced dysuria
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Over 18 years old Prostate cancer Candidate for radiation therapy (at the Radiotherapy Center of Shohada-e-Tajrish Hospital) Consciousness
Exclusion criteria:
Unconsciousness or unable to report dysuria Urinary catheter Urinary tract infection Diabetes Mellitus Dysuria A history of drug sensitivity Metastasis Chemotherapy at the same time Hematuria Severe Cardiovascular, Pulmonary, Hepatic and Kidney diseases that need some medical treatments Not participating in the study
Age
From **18 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple Randomization. Randomization is done using R software version 4.1.2, and we will use the randomization list generated using R software. In order to conduct this study, first, using the available method, patients who meet the conditions for entering the study, after completing the consent form, will enter the study until the number of calculated samples is complete. In the next step, in order to homogenize and control the background and confounding variables in the intervention and control groups, the block randomization method will be used to assign patients to two groups. For this purpose and according to the calculated sample size, 5 blocks of 14 blocks will be generated using R software. In each block, the interventions are randomly assigned to people with a ratio of 1:1. Since the shape of the drug and the placebo are completely similar and the labels on the cans of the interventions (drug or placebo) are prepared by a statistician (using R software) and sticked in the pharmaceutical laboratory, so, the participants and the researcher are all blind to it.
Blinding (investigator's opinion)
Double blinded
Blinding description
Double Blind. In this study, the barley product is prepared in the form of powder and is packed in a can and coded after putting a label. Placebo is also prepared with the same particle size and color as the drug in the same packaging as the drug and is coded. Therefore, until the encoding, it is not possible for the participants, principle investigator, healthcare providers, data collectors, outcome assessors, manuscript writers to distinguish the drug from the placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Sh. Aarabi Ave., Yaman Ave., Velenjak
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Tehran
Province
Tehran
Postal code
1985717443
Approval date
2022-09-12, 1401/06/21
Ethics committee reference number
IR.SBMU.RETECH.REC.1401.367

Health conditions studied

1

Description of health condition studied
Prostate Cancer, Radiotherapy-induced dysuria, Urogenital radiotherapy complications
ICD-10 code
Malignant
ICD-10 code description
C61

Primary outcomes

1

Description
Dysuria
Timepoint
Before intervention and 2, 4, 6, 8 weeks after intervention
Method of measurement
IPSS (International prostate symptom score) questionnaire

Secondary outcomes

1

Description
Quality of Life
Timepoint
Quality of life score before the intervention (week 0) 4 and 8 weeks after the intervention
Method of measurement
EORTC QLQ-PR25 Questionnaire (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire for Prostate Cancer)

2

Description
The number of phenazopyridine tablets which was used
Timepoint
2, 4, 6 and 8 weeks after the intervention
Method of measurement
Asking the participants

3

Description
Treatment satisfaction
Timepoint
8 weeks after the intervention
Method of measurement
It is measured by asking 1 Likert scale question (very high, high, medium, low and very low).

Intervention groups

1

Description
Intervention group: Twice a day, every 12 hours, one measure of "Maa-al-shaeer" (malted barley powder which was prepared by the school of Traditional Medicine of Shahid Beheshti University of Medical Sciences) is dissolved in a glass of lukewarm water and consumed after meals. Each measure of powder is equivalent to 7.5 cc of powder and the intervention period is four weeks from the start of radiation therapy and the follow-up period is four weeks (without intervention).
Category
Prevention

2

Description
Control group: Twice a day, every 12 hours, one measure of placebo powder (which was prepared by the school of Traditional Medicine of Shahid Beheshti University of Medical Sciences) is dissolved in a glass of lukewarm water and consumed after meals. Each measure of powder is equivalent to 7.5 cc of powder and the intervention period is four weeks from the start of radiation therapy and the follow-up period is four weeks (without intervention).
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Tajrish Hospital[9]9
Full name of responsible person
Vida Nazari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Vida Nazari
Position
Phd Student
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The study has not yet started, after the study is completed a decision will be made about sharing the participants' non-identifiable personal data.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available